

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA,)
)
Plaintiff,) Criminal Case No.
) 1:19-cr-00016-JPJ-PMS
vs.)
)
INDIVIOR INC. (A/k/a Reckitt)
Benckiser Pharmaceuticals)
Inc.) And INDIVIOR PLC,)
)
Defendants.)

TRANSCRIPT OF MOTION HEARING
HONORABLE JUDGE JAMES P. JONES PRESIDING
THURSDAY, FEBRUARY 27, 2020

A P P E A R A N C E S

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Proceedings taken by Certified Court Reporter and transcribed
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1 (Proceedings commenced at 1:31 p.m.)

2 THE COURT: Good morning, ladies and gentlemen. The
3 clerk will call the case.

4 THE CLERK: United States v. Indivior and Company,
5 et al. Criminal Docket 1:19cr16.

6 THE COURT: We're here today for oral argument on
7 the defendants' motion to dismiss. And I have read the
8 briefs. And I'll be glad to hear argument.

9 MR. LOONAM: Good afternoon, Your Honor. May it
10 please the Court, James Loonam of Jones Day on behalf of
11 Defendants Indivior.

12 The gravamen of any fraud claim is dishonesty. A
13 material omission, a material misstatement made to a victim to
14 obtain money or property. That's fraud.

15 In the present case the government is pursuing wire
16 fraud, mail fraud, and health care fraud claims against the
17 defendants all premised on the same purported scheme. And the
18 allegations contained in the superseding indictment can be
19 divided into two categories, as the government itself does in
20 paragraph 1 of the superseding indictment.

21 And, Your Honor, if you have a copy of the
22 superseding indictment in front of you, it might be useful.
23 If not, I have one for you.

24 THE COURT: I do.

25 MR. LOONAM: Yes, Your Honor.

1 So first, paragraphs 16 through 96 of the
2 superseding indictment concern alleged misrepresentations made
3 by the defendants in marketing Suboxone Film to doctors and
4 health care benefit programs; specifically, statements
5 regarding the reduced risk of pediatric exposure and diversion
6 for Suboxone Film. Now, we will vigorously fight these
7 allegations at trial. We believe the evidence will show that
8 Suboxone Film was, in fact, effectively designed to reduce the
9 risk of pediatric exposure and diversion. As an aside,
10 watching a room full of lawyers trying to pry open a package
11 of Suboxone Film was comical. But that's for trial because
12 those allegations of misrepresentations sound in fraud.

13 But the indictment contains a second set of
14 allegations that does not sound in fraud. Paragraphs 97
15 through 143 of the superseding indictment alleged that the
16 defendants did, quote, "Aid, abet, counsel, command, induce,
17 and procure," end quote, doctors who they knew were
18 prescribing in a careless and clinically unwarranted manner to
19 switch their prescriptions to Suboxone Film.

20 And that's paragraph 97, Your Honor, I would focus
21 you on, which is the introductory paragraph to the careless
22 prescriber allegations. So these allegations --

23 THE COURT: Why can't a conspiracy have different
24 objects?

25 MR. LOONAM: Well, a conspiracy can have different

1 objects. But if it's fraud conspiracy, the conspiracy, the
2 fraud claims need to be premised in dishonesty, in fraud
3 claims. You need to conspire to commit fraud.

4 THE COURT: Right.

5 MR. LOONAM: Now, if this was a Title 21 case and
6 there was a conspiracy, perhaps the prescribing practices of
7 the doctors would be relevant here. That's not what's
8 alleged. What's alleged is a conspiracy to commit health care
9 fraud, wire fraud, and mail fraud. And so the objects and the
10 means for those conspiracies have to be means to commit wire
11 fraud, mail fraud, and health care fraud as alleged. And when
12 you look at what the indictment states, and I think what's
13 telling here is if you go to, and I'll skip ahead to
14 paragraph 31 here, Your Honor, paragraph 31 is the paragraph
15 that lays out the scheme and artifice to defraud. Right?

16 So it says, "Between in or about 2006 and the date
17 of this indictment, the defendants, and their executives,
18 employees, and agents did devise and intend to devise a scheme
19 and artifice to defraud and to obtain money and property from
20 health care benefit programs by means -- here's laying out the
21 means -- "of materially false and fraudulent pretenses,
22 representations, and promises by..." And then it specifies
23 the means. All right?

24 "A. Making materially false and fraudulent --

25 THE COURT: I have it in front of me.

1 MR. LOONAM: Sure, Your Honor.

2 But if you look at A, B, and C, right? A, B, and C
3 all set forth making materially false and fraudulent
4 statements. Right? That's sounds in fraud. Undoubtedly
5 sounds in fraud. Right? It's a material statement that's
6 alleged to be misleading to obtain money or property.

7 But when you get to D, and that's the focus of our
8 motion, D is the focus of our motion. And the way this is set
9 up, A, B, C, D, that relates to subsections in the indictment.
10 So A corresponds to the subsection in the indictment, and B,
11 C, D, so forth. The allegations for D are paragraphs 96
12 through -- or 97 through 143. There's no allegation here of a
13 materially false or fraudulent statement. It's, "Marketing
14 Suboxone to health care providers to be prescribed and
15 dispensed in a careless and clinically unwarranted manner."

16 All right. So is there some dishonesty there that's
17 not set forth plainly in C? And we're left guessing.

18 But when you go to paragraph 97 of the indictment,
19 which is where the allegations of D pick up, what they say is
20 that -- and, Your Honor, I have it in front of me, so I won't
21 read the whole thing and try your patience, but the careless
22 prescription is only pled with respect to Indivior's
23 knowledge. It's not used to perpetrate the fraud. So it's
24 not as if this is a fraud where the careless prescription
25 practices as in a typical health care fraud scheme, the

1 prescription practices result in false Medicare claims going
2 out to defraud Medicare. That's sort of a, you know, bread
3 and butter health care fraud claim with false statements.
4 That's not what they say here. That is not what's pled.

5 What's pled is that the wild knowings that there
6 were careless prescription practices at certain doctors,
7 Indivior used lunches and dinners, it used a patient finder to
8 induce those doctors to switch to Suboxone Film. That's what
9 paragraph 97 says.

10 And the problem with that is is that dinners,
11 lunches, the Here to Help program, none of its dishonest.
12 None of it is. They don't allege that it's misleading at all.
13 They don't allege that these doctors were duped through the
14 lunches or the Here to Help program to then switch to Suboxone
15 Film. Right? That would be fraud if you duped the doctors
16 into switching to Suboxone Film, that's the allegations in A,
17 B, and C. D is of a different ilk.

18 THE COURT: Well, are you saying it's like bribery?
19 Is that -- instead of fraud?

20 MR. LOONAM: No. I mean -- well, look. What we
21 have is just what's pled in the indictment. Right? So we
22 have to go on the face of the indictment. But if you're
23 asking me if lunches and dinners with a doctor to get them to
24 use your products -- that's every-day business for a
25 pharmaceutical company. There's nothing -- there's nothing

1 unusual about that.

2 THE COURT: Well, that doesn't mean -- I mean,
3 politicians engage in every-day practices which I think most
4 of us might consider bribery. But, in any event.

5 MR. LOONAM: Well, Your Honor, look, if there was an
6 anti-kickback statute claim, they didn't bring it. All right.
7 If there was a bribery claim, they didn't bring it.

8 THE COURT: I understand your point. I was just
9 trying to see what you would characterize that as. It's not
10 fraud you say.

11 MR. LOONAM: It's not fraud.

12 THE COURT: You say it's nothing. You say it's just
13 good business practice they've charged.

14 MR. LOONAM: Maybe. If there's something nefarious
15 about it, it hasn't been pled. That's where we are.

16 The idea of taking doctors to lunch and dinner I
17 believe is accepted practice. In fact, I believe courts have
18 looked at this and I believe there are regulations that cover
19 the ability of pharmaceutical reps to take doctors to, you
20 know, reasonable lunches and dinners.

21 THE COURT: Well, I think so. I mean, the doctor I
22 go to, when I go to his office, a pharmaceutical rep is
23 bringing in lunch for all the staff.

24 MR. LOONAM: So, you know, in any event, the core
25 point for purposes of today, for this motion, Your Honor, is

1 that that's not a deceptive practice. That's not a fraud.
2 They don't -- and it's not alleged as such. Right? It's not
3 alleged that the doctors were duped by the lunches, that the
4 doctors were duped by the Here to Help program.

5 You know, the indictment is not a model of clarity
6 with respect to these -- how the government is using these
7 careless prescription practices. It's articulated a few
8 different ways. And so in our original motion --

9 THE COURT: So do you want me to strike D?

10 MR. LOONAM: Yes. Yes, D should be stricken,
11 Your Honor.

12 A, B, and C -- and it should be stricken for a
13 couple reasons. It's inflammatory, prejudicial, and doesn't
14 plead fraud. And to the extent the government uses an
15 argument in the alternative that, well, it shows you -- and
16 here, I'll quote them so I don't get it wrong.

17 The government argues that, "It serves as evidence
18 of Indivior's intent to defraud because it shows that Indivior
19 prioritized converting prescriptions of Suboxone Film over
20 safe and effective opioid-dependence treatment."

21 Well, Judge, that's nothing more than 404(b) other
22 acts evidence of propensity. They were willing to deal with
23 these doctors. And even though they knew, allegedly, they
24 were dealing with careless -- they were careless prescribers,
25 they still, you know, kept them on the Here to Help program;

1 they still gave them lunches; they still dealt with them.
2 That's 404(b) evidence of intent of other bad act evidence and
3 it's a total side show, Your Honor, that's going to lengthen
4 this trial by weeks. By weeks it will lengthen this trial.
5 Because we're going to need to get into the nitty-gritty of
6 the anti-kickback statute, the interactions with these
7 doctors, their prescription practices. You've already seen
8 some of this in the Rule 17 over the DEA's interactions with
9 them and their prescription practices having nothing to do
10 with the fraud. The government's merely alleging this
11 propensity evidence. Well, if they were willing to deal with
12 those doctors to increase their sales, then they must have
13 been willing to commit fraud. And that's a straight 404(b)
14 motion.

15 Moreover, what's contained in the indictment is not,
16 is not pled as evidence of intent. So to the extent the
17 government says, well, in the alternative, Your Honor, you
18 should keep this in because it's really evidence of intent,
19 it's not. It's pled as a means. It's not pled as intent. So
20 the government can't pivot and rescue its allegations in
21 trying to retask them by something that wasn't put before the
22 grand jury.

23 To the extent the government argues that this a
24 motion for summary judgment and that it's a matter of evidence
25 and sufficiency of the evidence, it's not. The indictment

1 says what it says. And the indictment does not allege that
2 the prescription, the careless prescription practices
3 constituted a misrepresentation, dishonest conduct in any way.
4 Simply doesn't do it.

5 This seems like -- what it does in effect is it
6 significantly prejudices the defendant by essentially trying
7 to dirty them up and tie them to alleged pill-mill doctors.
8 In order to overcome that, it's going to be a monumental
9 effort and, at the end of the day, doesn't even allege fraud.
10 So, yes, Your Honor, we think --

11 THE COURT: Well, what about the, not pill mill, but
12 doctors who dispense and, you know, bill for it to health care
13 companies, or the government, why would that not be part of
14 the scheme that they're helping these doctors do criminal
15 acts?

16 MR. LOONAM: Two answers to that. So the first is,
17 Your Honor, as we were racking our brains groping for what the
18 charges could be here and how this could fit within the
19 scheme, we said, well, perhaps that's what the government's
20 getting at, despite the language of paragraph 97 that said
21 that the aiding and abetting of the careless prescription
22 practices was to switch the doctors to Suboxone Film. That's
23 the allegation, not to aid and abet them in the fraud to --
24 with -- so we made that. We said, well, they don't actually
25 allege that, they don't allege that the doctors submitted

1 anything to Medicare or Medicaid or any insurance carrier that
2 was false or fictitious. They don't allege that any of these
3 referrals that the patients who were referred, that the
4 doctors billed, claimed that prescriptions were medically
5 necessary that, in fact, were not medically necessary. Could
6 that be a cognizable theory of fraud? Yes, of course, that
7 could be a cognizable theory of fraud. That's a bread and
8 butter health care fraud. They just don't allege that here.
9 And if they had, Your Honor, with respect to the doctors here,
10 it would be a separate scheme. It would be a separate scheme
11 than the scheme alleged in A through C. So A through C,
12 right? is that the doctors were duped by misrepresenting the
13 nature of Suboxone Film. And Suboxone Film was superior to
14 tablet because it would reduce the risk of pediatric exposure
15 and diversion. Right? And so in this instance the doctors
16 are victims.

17 With respect to the hypothetical charge that
18 Your Honor just cobbled together with respect to false claims
19 to Medicare, in that instance the doctors are coconspirators;
20 right? Not victims. They're not duped. They're in cahoots
21 with one another and defrauding Medicare. You have different
22 people responsible, different time periods. And, so, what you
23 wind up with is two separate schemes put before the jury,
24 wound together in one count, then you wind up with no
25 guarantee of having a unanimous verdict with respect to either

1 one. Right? So you have a complete due process problem with
2 duplicity where half the jurors could believe that there would
3 have been finding -- they could want to convict on the scheme
4 Your Honor just thought of and half could want to convict on
5 the A through C charge by the government about
6 misrepresentations, and you have a non-unanimous verdict and
7 we've gone through all this trouble and the count is no good.

8 And so, Your Honor, that's --

9 THE COURT: I mean, it's not -- you say on one side
10 they're victims, on the other side they're coconspirators.
11 But the scheme is to defraud health care benefit programs.

12 MR. LOONAM: And doctors and health care providers.
13 That's alleged throughout here. And the way that the health
14 care providers are -- so that's C, Your Honor. If you go to
15 C.

16 THE COURT: Well, I'm looking at paragraph 31.

17 MR. LOONAM: Okay. And then so paragraph 31 is the
18 introduction --

19 THE COURT: That's they devised a scheme to defraud
20 and to obtain money from health care benefit programs --

21 MR. LOONAM: Mm-hmm.

22 THE COURT: -- "by --

23 MR. LOONAM: So then go to 78. That's C,
24 Your Honor. That lays out in more detail what that means. So
25 paragraph 78. So from 2006 to the date of the indictment,

1 made statements and representations that Indivior was
2 discontinuing distribution of Suboxone Film (sic) due to
3 safety, when, in fact, it was discontinuing the tablet to
4 delay the FDA's approval of generic tablet. And it goes on
5 about what that means with respect to -- and that's here. The
6 Medicaid, you know, administrators and others. That's what is
7 set forth in the structure of this indictment.

8 There's nothing with respect to Drs. A though D or
9 the careless prescription practices that are spelled out in
10 this indictment that those individuals defrauded health
11 benefit programs.

12 Your Honor, again, we're groping in the dark to try
13 and figure out what was charged here. We said, that's not
14 properly pled in this indictment. They don't allege that, you
15 know, the doctors defrauded Medicare. They didn't make any
16 allegations about -- and what the government came back with
17 was that's a straw man. We're not alleging that. That's a
18 straw man. We're not alleging that you aided and abetted
19 other crimes of these doctors. That's a straw man. What
20 we've alleged, it's kind of -- if you read the reply, it's a
21 little bit of ishkabibble means ishkabibble because, it says,
22 "We've alleged the scheme we've alleged."

23 THE COURT: Well, I think the government says this
24 charge reflects Indivior's referrals and aid to doctors were a
25 means of the scheme and artifice to defraud.

1 MR. LOONAM: Exactly. "Were a means of the scheme."

2 But what does that mean? When they talk about the
3 scheme -- and again, go to paragraph 97. When it talks about
4 the -- so no later than April 9th, 2009, which, by the way,
5 predates when film hit the market, and on the record during
6 the bill of particulars argument, the government noted that
7 the practice of dealing with the careless prescribers and the
8 Here to Help program, according to the government, predated
9 the introduction of film and they had the same practice with
10 respect to tablets.

11 "Indivior, its executives, employees, agents, did
12 aid and abet, counsel, command, induce, and procure physicians
13 in various positions throughout the United States who they
14 knew were prescribing buprenorphine-containing drugs to more
15 patients in the allotted time at a daily dose higher than
16 24 milligrams and in a careless and clinically unwarranted
17 manner to switch their prescribing to Suboxone Film."

18 That's the scheme they're alleging.

19 THE COURT: All right. And that, as a result, the
20 physicians were overprescribing the medication.

21 MR. LOONAM: Well, not as a result. The
22 overprescribing is charged as knowledge. You were aware of
23 this, and even though you were aware of it, you continued to
24 deal with them because you wanted them to switch to film. And
25 it's a juxtaposition of the knowledge of the their

1 overprescribing juxtaposed against --

2 THE COURT: My point was, I guess, if they're
3 overprescribing, they are defrauding Medicare.

4 MR. LOONAM: No.

5 THE COURT: Medicaid.

6 MR. LOONAM: No. No, no, no, no. No. No. First
7 of all, that is not alleged in here. Right? That is not
8 alleged in here. And the fact that somebody is over their
9 DATA 2000 cap is not defrauding Medicare. That's not the law.
10 That's not what's pled.

11 We're struck with what their -- the fact that we're
12 here two months before trial and it's unclear as to what the
13 scheme is, even though the government had a chance to reply,
14 and Your Honor read that portion that should crystallize what
15 the scheme is, you know, demonstrates that there's a serious
16 problem I think with this indictment.

17 THE COURT: The government criticizes the defendants
18 for piecemealing these motions to dismiss, that you could have
19 done this from the beginning and you're overwhelming them.

20 MR. LOONAM: Your Honor, I mean, so we've answered
21 this in our papers multiple times now. The government tried
22 to get an order to show cause on this, you know, that
23 Your Honor rightfully rejected. The idea that we've
24 sandbagged the government by filing this motion five months in
25 advance of trial is completely without merit. You know, look,

1 the government had a hard deadline for its Rule 16
2 disclosures. Hard deadline. Not substantial completion, hard
3 deadline. All Rule 16, all Brady, all Giglio by August 9th of
4 last year. We're still receiving supplemental productions as
5 of a few weeks ago. We're not running to this court saying
6 the government sandbagged us. Of course not. The government
7 is acting in good faith. It's identified additional
8 information that should have been produced and it's now
9 producing. That's the nature of litigation. In this
10 instance, you know, we had a motion to dismiss pending that
11 took some time for the parties to litigate. That motion would
12 have mooted all other issues.

13 The government, you know, wound up superseding the
14 indictment to moot it. And as soon as Your Honor issued a
15 decision on the original motion to dismiss, a month later we
16 filed this motion, five months in advance of trial. And, so,
17 clearly in the context of Rule 16, the scheduling order is not
18 sacrosanct for the government, nor should it be, because it's
19 just unreasonable. And we get that. And it's fine. But it's
20 not fair for them to say there should be sacrosanct on the
21 other side, especially when it applied to the original
22 indictment. There was a superseding indictment that the
23 government used to moot our original motion to dismiss. We
24 noted in all those papers that we anticipated filing an
25 additional motion to dismiss.

1 And, frankly, this indictment, if you look at the
2 different ways that this theory is articulated, it took a
3 little time to flush out. In fact, we tried to flush it out
4 in the bill of particulars motion to give the opportunity
5 to crystallize. And that was denied. But, during the course
6 of that, the government made statements that sort of
7 crystallized their theory here that made it clear that it
8 doesn't sound in fraud.

9 And then moreover --

10 THE COURT: You've convinced me.

11 MR. LOONAM: Your Honor, yes.

12 THE COURT: Let's go on to something else here.

13 Your argument, I guess, is connected to your aiding
14 and abetting argument as to the other counts where they add on
15 in the count, you know, Section 2, aiding and abetting. And
16 there's really no -- I'm confused, like you are, what that
17 means. Maybe they'll tell us.

18 MR. LOONAM: So look, Your Honor, to the extent the
19 government wants to charge Indivior under 18, U.S.C.,
20 Section 2 for mail fraud, wire fraud, health care fraud, under
21 A through C, I mean, that's sort of typical government
22 practice. You know, that's sort of -- that's accomplished by
23 the statutory citation. The problem here is that they've used
24 the language of 18, U.S.C., Section 2 in the indictment to say
25 that we aided and abetted, then they go on to quote the rest

1 of Section 2, the careless prescription practices. Right?
2 And all of that to switch those doctors to Suboxone Film.
3 That is not allowed. Right? Because the careless
4 prescription practices hasn't alleged that the doctors had
5 committed a primary violation --

6 THE COURT: It sounds like, it sounds like in their
7 response they're really characterizing aiding and abetting.
8 They say "aid." They're sort of using a non-legal
9 characterization of what aiding and abetting is. They are
10 helping the doctors be careless.

11 MR. LOONAM: So, Your Honor, that is the term they
12 use. They don't -- it's not articulated as when we said aid
13 and abet, command, procure, and then quoted 18, U.S.C.,
14 Section 2, what we really meant was colloquially helped.

15 THE COURT: Right.

16 MR. LOONAM: Right? They don't say that. They
17 don't address the argument at all. I agree, Your Honor,
18 implicitly what they say --

19 THE COURT: They charge in its instruction to
20 reflect Indivior's referrals and aid to the doctors.

21 MR. LOONAM: Yes. It ignores the fact that they cut
22 and pasted the language from 18, U.S.C., Section 2, which has
23 legal meaning. Right? It has legal significance. Talk about
24 being confusing to a jury when they are going to be instructed
25 by Your Honor on the meaning of Section 2 and all those terms,

1 then it's thrown in colloquially, that is not appropriate.
2 Right? So I think that's subsumed into, you know, if
3 Your Honor strikes the allegations of D because they don't
4 sound in fraud, which there's no basis. And it's apparent
5 from the face of the indictment you have A through C alleging
6 misstatements and dishonesty to obtain money or property. And
7 D just says they aided and abetted careless prescription
8 practices to switch to Suboxone Film. Aiding and abetting
9 careless prescription practices is not fraud.

10 Your Honor's correct, if the government had alleged
11 that, you know, Indivior knew that this doctor would file a
12 claim and assert that this was medically necessary when, in
13 fact, it wasn't. Indivior referred the patient and had a
14 shared purpose in accomplishing that goal. Yeah, that sounds
15 like a claim in fraud to me to obtain money or property. This
16 doesn't do that.

17 THE COURT: Well, I think I understand your
18 arguments, unless you have a different one.

19 MR. LOONAM: I think that's all for now, Your Honor.

20 THE COURT: I'll let you respond.

21 MR. LOONAM: Otherwise, we'll rely on our papers.

22 Thank you, sir.

23 THE COURT: All right. Thank you.

24 MR. MAYER: Thank you, Your Honor. Albert Mayer on
25 behalf of the government.

1 THE COURT: So explain what marketing Suboxone Film
2 to health care providers to be prescribed and dispensed in a
3 careless and clinically unwarranted manner, how is that a
4 fraud means?

5 MR. MAYER: Yes, Your Honor.

6 So to just take a step back in the facts. Indivior
7 determined that certain doctors were issuing clinically
8 unwarranted prescriptions for Suboxone, an opioid. And the
9 clinically unwarranted language is the exact language that
10 their medical people use and that went to their medical
11 director. So they determined that. They identified the
12 doctors. And there were other information they had about
13 those doctors. Like the ones we used, Dr. A had 800 people on
14 Suboxone at one time. And Dr. C had a Vegas-style cash
15 machine in his office. Dr. D had something like 70 percent of
16 the patients on unusual high doses. So they had that
17 information and make the conclusion these people are issuing
18 clinically unwarranted prescriptions.

19 At the same time, the company has something called
20 the Here to Help service which connects patients, ostensibly
21 connects them to doctors for opioid-dependence treatment. And
22 they hold it out there as a way for patients to receive
23 appropriate opioid-dependence treatment. And then when people
24 call the Here to Help program to receive this referral for
25 opioid-dependence treatment, the company refers them to the

1 same doctors that have been identified as issuing clinically
2 unwarranted opioid prescriptions, having 800 patients, and
3 Vegas-style cash machines.

4 That referral -- this is the first of several
5 arguments I'm going to make. That referral is a fraudulent
6 representation. And there's no basis to hold as a matter of
7 law that that's not fraudulent. The jury, it's their province
8 to determine whether it's fraudulent to knowingly send a
9 patient to a doctor you've determined is issuing clinically
10 unwarranted opioid prescriptions to get money, which is the
11 reason they were making the referrals.

12 THE COURT: So they were defrauding patients.

13 MR. MAYER: Sorry. No, Your Honor. It's a fraud on
14 the payers.

15 THE COURT: I'm sorry?

16 MR. MAYER: That's a fraud on the people who pay for
17 the prescriptions. Because those folks --

18 THE COURT: So they're defrauding the health care
19 benefit programs by referring patients to doctors that are
20 going to do what?

21 MR. MAYER: That they have determined issued
22 clinically unwarranted opioid prescriptions.

23 I guess one sort of hypothetical, it's not a perfect
24 analogy, but may be helpful to understand all this. If we all
25 went down to the hospital right now and there is someone

1 outside the exit, and we say, if you need appropriate pain
2 treatment, I can refer you to someone. Go to Dr. Smith for
3 your pain treatment and that person knows that Dr. Smith is
4 issuing clinically unwarranted opioid prescriptions and that
5 person is making money off the prescriptions, it can be
6 fraudulent on the part of the fraud scheme.

7 THE COURT: So the government's theory is the
8 defendants had these doctors who were overprescribing, they
9 believed, opioid medications.

10 MR. MAYER: Right.

11 THE COURT: And they wanted to boost those doctors
12 even more so they would buy more Suboxone Film; right?

13 MR. MAYER: Yes, Your Honor.

14 THE COURT: And so, in turn, that would defraud the
15 health care provider -- health care benefit programs. Right?

16 MR. MAYER: Yes.

17 Sorry.

18 THE COURT: Because the theory is that Indivior knew
19 that these doctors were overprescribing and would submit
20 unwarranted billings to health care providers? I mean, health
21 care benefit programs?

22 MR. MAYER: We couldn't say that they knew that
23 would happen, we're saying that was a scheme. It was part of
24 the fraud scheme for that to happen.

25 Of course, the statute talks about trying to obtain

1 money from health care benefit programs by means of false or
2 fraudulent representations.

3 THE COURT: Explain to me again how this works.
4 What is the -- what is the government -- what are you going to
5 tell the jury about this aspect of the case?

6 MR. MAYER: Sure.

7 THE COURT: So our proof is that Indivior knew that
8 these doctors were overprescribing. And so they had these
9 things that they did to get these doctors to overprescribe
10 even more and that defrauded health care benefit programs.

11 MR. MAYER: Yes. The things they --

12 THE COURT: That's what -- this is a health care
13 fraud statute.

14 MR. MAYER: That's correct, Your Honor.

15 The victims, just to counter something the
16 defendants have said, the victims are the health care benefit
17 programs. That's the victim of health care fraud. And that's
18 the only victim that we're talking about.

19 THE COURT: Right.

20 MR. MAYER: So yes, if the -- well, not if. The
21 company did determine that particular doctors were issuing
22 clinically unwarranted opioid prescriptions based on
23 information that the company received. And then the company
24 told patients, hey, if you need opioid-dependence treatment,
25 come to us, we'll hook you up with a doctor. Then when the

1 patients came to them, they hooked them up with these doctors
2 they identified as issuing clinically unwarranted opioid
3 prescriptions, or switch to those doctors to get money from
4 health care programs.

5 And the other representation they make, "aid," which
6 was discussed with the defense, we mean aid in the sense of
7 helping. They were also providing those same doctors with
8 information about how to treat more patients, get insurance
9 claims.

10 THE COURT: Well, shouldn't you have added Section 2
11 to the charges just reflectively? Because just helping is not
12 the legal definition of aiding and abetting.

13 MR. MAYER: We included the language --

14 THE COURT: They don't have the same intent and so
15 on.

16 MR. MAYER: That's correct. We did use the
17 statutory language, the aid, abet, counsel, command, induce,
18 and procure language to mean all the ways that somebody can be
19 understood to aid another. We didn't mean it in the technical
20 legal sense in that paragraph that was under discussion
21 earlier. We meant they were helping the doctors to get more
22 patients, and they were doing it to get those doctors to
23 switch to film. And we think those representations that were
24 made to the doctors, the statements and the aid, and most of
25 all those referrals to the patients, those are fraudulent.

1 Those are means of a fraudulent scheme.

2 THE COURT: Okay. You mean that the -- what about
3 this stuff about dinners and freebies and things like that?

4 MR. MAYER: Sure. All part of the aid that the
5 company was providing to the doctors. And it all -- in the
6 interest, it's sort of telling the full story of what happened
7 with these doctors. The company had the information about the
8 doctors but for years -- they had, you know, the indictment
9 says 2009, that's about the earliest we see they have this
10 information. And sometime thereafter, I believe early 2010,
11 according to the e-mails, says clinically unwarranted
12 prescriptions by these doctors. They're identified at that
13 time. Then for years the company continues, and the evidence
14 will show this, the company continues to have people go out
15 and treat them to dinner, lunch to talk about how to get
16 insurance claims paid. And as I've said, most of all
17 continues to refer patients their way having determined that
18 the doctors are issuing clinically unwarranted opioid
19 prescriptions. And I don't think there should be a holding
20 that that's not fraud, that's not a fraudulent act.

21 I heard the defendants' argument that to the
22 defendants it doesn't sound in fraud to them. It fits the
23 statute. So there's no basis to say, to hold just as a matter
24 of law it's not fraud to refer somebody to clinically
25 unwarranted opioid prescriptions -- strike that. To a doctor

1 issuing clinically unwarranted prescriptions to make money on
2 the prescriptions the doctor writes. Just hold as a matter of
3 law that's not fraudulent. We would think that's the jury's
4 province to determine whether or not that's fraudulent.

5 And one of the cases we cited, which was the closest
6 on point for this idea is with the *Swain* case from the Western
7 District of North Carolina. The defendant argued hey, the
8 government found some images on my computer, but they're not
9 pornography. The Court's response in that was it's for the
10 jury to decide whether or not that's pornography. We think
11 the same principle applies to this. It will be for the jury
12 to determine whether those referrals are fraudulent based on
13 what the company knew at the time and where they're going to
14 go to dinners and lunches and all the rest to doctors they
15 made that determination about in order to get money by
16 switching the doctors to film.

17 THE COURT: And what is the fraudulent
18 representation exactly?

19 MR. MAYER: Well, the easiest one to point out is
20 the referral. The statement to the patient that we, you know,
21 we refer you to a doctor for your opioid-dependence treatment
22 knowing that doctor is actually one identified as writing
23 clinically unwarranted opioid prescriptions is a fraudulent
24 representation. That's the best example.

25 And the other pretenses and representations in the

1 meetings with doctors to aid them --

2 THE COURT: You mean implicit is, "This is a good
3 doctor for you to go to" is fraud because they knew it wasn't
4 a good doctor for the patient to go to?

5 MR. MAYER: Exactly. Yes, Your Honor.

6 And the jury could find that's not fraudulent. But
7 it could be. It could be part of a fraudulent scheme.
8 There's no legal reason it can't be.

9 So that's the main issue that was argued by the
10 defendants.

11 And I'd like to touch on four other points, and I'll
12 do them more quickly. The first is duplicity. This idea that
13 the scheme which had one person -- or one actor running the
14 whole thing, Indivior, that all occurred during the same time
15 period; the marketing of Suboxone Film. They point out that
16 the Here to Help program started before the market. That's
17 because they were rolling it out in advance of the market so
18 they could get the program started and have it up and running
19 when the film reached the market. But it's the same time
20 frame of the marketing of the film; for the same purpose, to
21 switch doctors to the film; same offenses, health care wire
22 fraud; and the same nature, it's all pharmaceutical marketing
23 practices. The idea that's two different offenses that need
24 to be charged separately is not supported by the case law.
25 The case law was about -- for instance, one of the cases that

1 was pointed out in the briefing was the *Witasik* case from the
2 Western District of Virginia. That's where a single person
3 was charged with some insurance frauds against multiple
4 insurance companies at one timeframe and then tax fraud at a
5 different time. Those are different offenses. So that was
6 found to be -- have a duplicity issue. But these are the same
7 offense, same person, same time frame. And the cases don't
8 say that's a duplicity problem. And there's really no risk of
9 confusion, ultimately, at the end of the day, questions that
10 the jury could be confused about the scheme, and there's no
11 reason to think they would be.

12 Third, I'll say briefly. Even if the Court were to
13 reject the idea that it could be -- that there were -- the
14 jury can find fraudulent representation in the referrals and
15 the aid, it's still not surplusage because that, those
16 activities are evidence of the company's intent and what it
17 was trying to do in referring patients and aiding these bad
18 doctors. They were trying to increase film prescriptions and
19 they were doing it any way they could. And they were trying
20 to make money from the health care benefit program through
21 film. So it shows their intent. It's real convincing on
22 intent because of how dangerous it is to send somebody who
23 comes for opioid-dependence treatment to a doctor who's
24 writing clinically unwarranted prescriptions.

25 Fourth is waiver. We spent five months on the first

1 motion -- I shouldn't say we spent five months. The
2 defendants had five months on their first motion to dismiss.
3 The date of the original indictment was April 9th, and they
4 had, pursuant to the scheduling order, until December 10th.
5 That's a five-month period. There were 75 pages of briefing,
6 80 minutes of oral argument, and the Court issued a 21-page
7 decision.

8 And that was a long time ago now. Here we are a
9 couple months from trial and we're doing it again. And we're
10 talk about things that were perfectly available for the
11 defendant to argue back last summer over the course of five
12 months. That has jammed up the scheduling of the case a bit.
13 There was a lot else due and there's been a lot of other
14 briefing in the last couple months, and there was no need to
15 relitigate this. It could have been litigated back five
16 months ago.

17 Just looking at the criminal rules, I understand and
18 agree with defense counsel's observations, they're not meant
19 to be so rigid that a person can't supplement something based
20 on new evidence or new argument. But there's no new evidence
21 or argument here. And the rules say, the Rule 12(c)(1) says
22 there can be a scheduling order and the other says scheduling
23 order can be changed for good cause. There's no good cause in
24 this instance. These arguments were available last summer.
25 There were five months. The superseding indictment didn't

1 change that.

2 THE COURT: Well, what does the scheduling order
3 say?

4 MR. MAYER: The scheduling order says that a motion
5 challenging the sufficiency of the indictment is due no later
6 than September 10th, 2019. And that was five months after the
7 indictment.

8 And there was a superseding indictment in between,
9 but it just changed the ten words of paragraph 143. So these
10 arguments weren't affected. So there was this full and fair
11 opportunity last summer to have a hearing on all this. And it
12 was all well-heard. It was a big 75-page briefing, 80-minute
13 oral argument kind of deal.

14 THE COURT: Well, your argument is based on the
15 scheduling order?

16 MR. MAYER: That's correct, Your Honor.

17 THE COURT: I mean, it's not just some general idea
18 of waiver. Without the scheduling order -- well, the
19 scheduling order is the basis of your motion, or your defense
20 or argument?

21 MR. MAYER: 100 percent.

22 That's correct. We rely on the *Mathis* case, which
23 distinguishes in the sense that someone waited all the way
24 until trial. The reason we rely on it, the Fourth Circuit
25 said, if you break the schedule, you need to have good cause.

1 And here there was a scheduling order in place, it was
2 followed, then they broke it. And there's no cause. No cause
3 has been shown. We don't even know what the cause is supposed
4 to have been for why this was filed so late. They say it was
5 a superseding indictment. The superseding indictment doesn't
6 change any of the issues we're arguing about today, so that's
7 not cause.

8 Finally, briefly, the grand jury issue. They've
9 argued again, they've cited a number of cases where
10 prosecutors told the grand jury there was a time limit to
11 return an indictment. There's -- that didn't happen. There's
12 no evidence that happened here. So it's just totally
13 inaccurate to raise that. Those cases don't apply and there's
14 no basis to reopen that issue.

15 One last point. There's been a lot of talk about,
16 well, in referring patients to doctors that we determined were
17 issuing clinically unwarranted prescriptions. Well, we have
18 to know what the DEA thought about it and we need to know what
19 SAMSHA and these other agencies thought about it. We're not
20 alleging they referred patients to doctors that they thought
21 the DEA had made a determination about or not, or they thought
22 that SAMSHA made a determination, that's not what the
23 indictment is. The indictment is very specific. They were
24 referring patients to doctors they had determined were issuing
25 clinically unwarranted prescriptions because they wanted the

1 money from switching those doctors to film. And so all the
2 talk about what folks in government may or may not have
3 thought or known, the company didn't know, it's outside the
4 scope of what's indicted.

5 THE COURT: It may be apparent, but what do you mean
6 by switching them to film? I mean, I understand that film is
7 the issue here, but "doctors who are overprescribing opioids,
8 switching them to film," what is the -- where is the switching
9 to film related to fraud?

10 MR. MAYER: Yes, Your Honor. So the situation the
11 company was in, as reflected in the e-mails, the
12 communications of its executives, is that they had a tablet,
13 Suboxone Tablet, that they were anticipating generic
14 competition and that that business line was going to disappear
15 pretty rapidly once generics came in. So they developed
16 Suboxone Film, what they called it: A switch campaign, a
17 switch blitz. Their business goal was to get doctors to
18 switch to prescribe Suboxone Film instead of tablets. That
19 was the business goal that the company had because that was
20 the only way they were going to make money in the future.
21 They had determined their future profit was going to be based
22 on the film. There wasn't going to be much in the tablet.

23 THE COURT: Right.

24 MR. MAYER: So the aspects that -- the aspects were
25 designed to switch doctors over to the film so they could get

1 money for the film prescriptions in the future.

2 And it wasn't -- it wasn't just telling doctors that
3 the film is safer, it was telling doctors, you're going to end
4 up on the witness stand defending your prescription due to the
5 death of a child. It was telling doctors, you're going to
6 cause baby deaths; telling them that film weeds out drug
7 seekers and protects the community.

8 I mean, these are -- it's been sort of summarized by
9 the defendants, oh, they said it was safer. That's not the
10 evidence. The evidence was these specific things were said.
11 And when they gave the doctors graphs, they took lines out of
12 the graphs so the doctors couldn't see all the data. That's
13 what the graphs were all about. And when they sent data from
14 Medicaid to them, they just falsified it. They just changed
15 the numbers. So it's not just, oh, I don't think they're
16 safer, maybe there's data about that. That's not what the
17 allegation is.

18 THE COURT: Right. But these doctors who were
19 overprescribing opioids switching to film, that's the
20 connection I don't understand.

21 MR. MAYER: Sure. They had a -- there was a
22 meeting -- sorry.

23 THE COURT: In other words, were those doctors --
24 they thought that they would be a better market for film
25 because why?

1 MR. MAYER: No. It was because those doctors were
2 really important to the bottom line because they issued lots
3 and lots of prescriptions, and they had data analysis showing
4 what a big impact these high-prescription doctors had on
5 revenue. And so it was a big priority to get these
6 high-prescribing doctors to switch over to the film. If they
7 didn't, it would be a lot of lost money.

8 THE COURT: High prescribing of what, the tablet?

9 MR. MAYER: Correct. Yes. These were doctors who
10 were high prescribers of tablets; buprenorphine tablets, so
11 Subutex and Suboxone. They wanted to get those prescribers
12 switched so that they were doing high prescribing of the film.
13 In that same time, they identified those high-dose prescribers
14 were writing to 800 people at a time in the case of Dr. A.
15 But they really wanted to switch them to the film so they
16 could get the money on film prescriptions going forward with
17 Dr. A.

18 THE COURT: And the allegation is that they knew
19 these doctors were-- shouldn't have been prescribing so much?

20 MR. MAYER: Correct. That the doctors shouldn't
21 have been prescribing so much, shouldn't have been prescribing
22 such high doses, and other things that are more anecdotal,
23 like the Vegas-style cash machine with Dr. C. Dr. B had lost
24 the license to prescribe in Kentucky and they continued
25 referring patients to these folks. They did it because they

1 wanted to get those folks to switch onto film. That was the
2 future profit source for the company. They wanted to be in
3 the good graces of those doctors so those doctors would switch
4 to the film.

5 THE COURT: Okay. Let me hear from the other side.

6 MR. MAYER: Thank you, Your Honor.

7 MR. LOONAM: Sorry, Your Honor, I just wanted to get
8 down the last bit that Mr. Mayer stated to Your Honor, which I
9 think is probably, you know, as far as what the allegations
10 are, sums up the allegations that, "They wanted to be in the
11 good graces of the doctors so they would switch over to film."
12 That's not fraud. There's no dishonesty. They weren't duped.
13 There's no allegation in the indictment that the doctors
14 submitted medically unnecessary prescriptions. That would be
15 a normal health care fraud case. That's not alleged here.

16 The government --

17 THE COURT: Well, I thought in response to my
18 questions the theory was that they were referring patients,
19 that the fraud was telling patients you ought to go to see
20 this doctor.

21 MR. LOONAM: So let's --

22 THE COURT: And their intent was because these
23 doctors were high prescribers that they would make more money
24 from the health care benefit programs that paid for these
25 prescriptions.

1 MR. LOONAM: So let's -- this motion is on the face
2 of the indictment. And let's look at the face of the
3 indictment as to what it says about these referrals and the
4 Here to Help program.

5 No allegation that doctors that switched over to
6 film were prioritized in the Here to Help program. To go
7 outside the indictment, you know why? Because it didn't
8 happen. No allegation that doctors who were high prescribers
9 that are the focus of this were promoted in these Here to Help
10 referrals, that they were given priority over other doctors as
11 a result of their high prescribing. It's not alleged to go
12 outside the indictment. You know why? Because it didn't
13 happen.

14 This Here to Help program was based on geographic
15 proximity. And we don't need to go outside the indictment,
16 because that's what's alleged. Solely geographic proximity.
17 Someone calls, I need a Data-2000-waived doctor, here is my
18 zip code. Here are the doctors, in a menu that comes up
19 there, closest to you.

20 No link in this indictment between those referrals
21 and any dishonesty, any misstatement. It's just nonexistent
22 in the indictment. So to the extent that the government now
23 gets up and says, well, those referrals were dishonest
24 because... That is not contained in the indictment. And it's
25 also inconsistent with what they affirmatively say, which is

1 that they were based on geographic proximity.

2 So they're juxtaposing knowledge of what the company
3 or what somebody at the company said, "clinically unwarranted
4 prescriptions." Right? They're saying they continued to
5 refer patients to them based on geographic proximity. That's
6 not fraud. There's no misleading going on there. They don't
7 tie that referral to any claim that there was a medically
8 unnecessary script written. It doesn't happen.

9 And, so, then they still haven't articulated a
10 theory of fraud. And that -- and according to the government,
11 the referrals, that's the best they got to keep digging. And
12 if it doesn't fit -- the government said, well, there's no
13 basis to say that that's not fraud. I beg your pardon. You
14 need a scheme to defraud. A means for fraud involves
15 dishonesty. The jury instructions are you have to find a
16 material misstatement, a material omission, or dishonesty to
17 obtain money or property.

18 And what this is is it looks like the government
19 going back to, you know, when we were last before Your Honor
20 in the context of where this investigation started and the
21 search warrant affidavit. This case started as an
22 investigation of Title 21 into a more typical health care
23 pill-mill case that they weren't able to make. They got
24 halfway there. And they've just decided to append those
25 allegations because they have some evidence of it into this

1 and shoehorned it, tried to shoehorn it into fraud. But it's
2 not fraud. If the government had a Title 21 case, it would
3 have made it. It didn't. And they can't prejudice Indivior
4 by trying to associate us with pill mill -- alleged pill-mill
5 doctors when it hasn't made the allegations that would allow
6 them to do that.

7 So to the extent it says it's still evidence of
8 intent, you've heard my argument on that. It's not pled as
9 evidence. It's pled as a means to commit fraud. So it can't
10 survive in the indictment in this form. And to the extent the
11 government wants to bring evidence, the time for 404(b) notice
12 under the scheduling order has passed. That being said, given
13 the developments here, the government should promptly file
14 notice of 404(b), its intention to introduce evidence under
15 404(b) of the activities with respect to these doctors, and
16 then we could have this discussion in the context it belongs,
17 which is an evidentiary discussion about its probative value
18 of the fraud that's alleged with respect to A through C versus
19 its prejudice and the side show that it is going to cause
20 during this trial.

21 And to the extent that the government says, well,
22 SAMSHA and DEA are irrelevant, they are not, Your Honor,
23 because they have alleged, not only the fact that Indivior
24 believed that the doctors' prescriptions practices were
25 clinically unwarranted, it alleges that, in fact, those

1 practices -- the doctors were prescribing in a clinically
2 unwarranted manner. Right? So it's different. It's not just
3 knowledge. They're saying as a matter of fact the doctors
4 were prescribing. To the extent the DEA is in there, they
5 have relevant evidence as to what the prescription practices
6 were.

7 They did a DATA 2000 inspection of every doctor who
8 has waived. So that's going to be irrelevant.

9 And look, to the extent the government has all this
10 great evidence that these doctors are so bad, prescribing in a
11 clinically unwarranted manner, you know, they have Vegas-style
12 cash machines that they love to bring up as prejudice, those
13 doctors are still on a government list, the SAMSHA list, that
14 did the same exact thing, that refers people to -- based on
15 geographic proximity to a DATA-waived doctor. You can do that
16 today regarding those same doctors. So they're letting the
17 dog walk them.

18 THE COURT: Well, as you say, we have to look at the
19 face of the indictment for your arguments.

20 MR. LOONAM: Undoubtedly, Your Honor.

21 THE COURT: We've gotten into the evidence. I
22 understand that. It's helpful for me to understand a little
23 bit about the theories. But, anyway.

24 MR. LOONAM: Your Honor, look, it was responding to
25 the government's arguments. But, I agree, you have to look at

1 the four corners of the indictment. And if you look at the
2 four corners of the indictment, what's said about those
3 referrals is that they were based on geographic proximity, not
4 that they were done to promote doctors who were high
5 prescribers in order for them to submit medically unnecessary
6 claims to defraud the health care benefit provider. That
7 is -- that's not the allegation. That does not -- that is not
8 in here.

9 So, to the extent it was done to get in the good
10 graces of the doctor to get them to switch to film, that's not
11 fraud. You take somebody to dinner to get in their good
12 graces, not fraud. You allow somebody to continue to
13 participate in a program that's available -- this, by the way,
14 the Here to Help referral program, it's not -- every doctor
15 that wanted to opt into it could get into it who was DATA
16 waived. So it's not as if these referrals -- it's not as if
17 these referrals were specific to doctors that were
18 overprescribing. Right? These are doctors who DATA waived,
19 who opted in, who were close in proximity as a matter of just
20 where they were located to the people that called in. And
21 that's what's alleged. And that does not sound in fraud
22 because it's not dishonest, it's not a misrepresentation. The
23 idea of a referral being inherently dishonest or a
24 misrepresentation, that's simply not alleged in here.

25 So, one moment, Your Honor.

1 Sorry, I just wanted to check my notes.

2 Thank you, Your Honor.

3 THE COURT: Thank you.

4 Well, thank you, counsel. I'm going to take the
5 motion under advisement.

6 Is there anything else we need to talk about in
7 relation to this case?

8 We're going fast toward trial and everything's
9 groovy.

10 MR. MAYER: Only one, briefly, Your Honor. We are
11 working -- we proposed to the defendants a stipulation that a
12 number of its own e-mails that it produced in response to
13 doctors would be admissible. And we asked for a response and
14 it hasn't -- that time hasn't passed yet. But if we're not
15 able to work that out, we anticipate making a motion in limine
16 to find certain e-mails of the company that were produced in
17 response to doctors by the company are admissible. So that's
18 something that may be around the bend, but hopefully we can
19 work it out between the parties.

20 THE COURT: We have a pretrial conference set in
21 this case, as I recall, and I believe in the scheduling order
22 there are time limits for filing motions in limine prior to
23 the pretrial conference.

24 MR. MAYER: That's correct, Your Honor.

25 THE COURT: Okay. Well, thank you, counsel.

1 I'm not going to come down and shake your hands,
2 just to make sure we don't spread any viruses. And you people
3 that come from distant places, we're not so sure about that.

4 MR. LOONAM: Totally understandable, Your Honor.

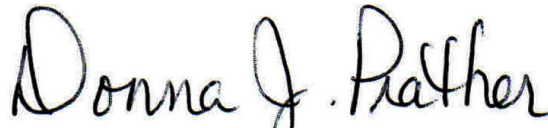
5 THE COURT: But it's nice to see you all, and we'll
6 recess court.

7 (Proceedings concluded at 2:35 p.m.)
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REPORTER'S CERTIFICATE

I, DONNA J. PRATHER, do hereby certify that the
above and foregoing, consisting of the preceding 43 pages,
constitutes a true and accurate transcript of my stenographic
notes and is a full, true and complete transcript of the
proceedings to the best of my ability.

Dated this 28th day of February, 2020.

A handwritten signature in black ink that reads "Donna J. Prather". The signature is written in a cursive, flowing style.

DONNA J. PRATHER, RPR, CRR, CBC, CCP
Federal Official Court Reporter